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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/486,516	06/07/2000	HEINZ REDL	BHV-317.01	5257

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EXAMINER
MELLER, MICHAEL V

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 07/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/486,516	REDL ET AL.	
	Examiner	Art Unit	
	Michael V. Meller	1651	

-- The MAILING DATE of this communicati n appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 April 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-73* is/are pending in the application.

4a) Of the above claim(s) *31,32,34,35,43-50,52,53 and 61-69* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29,30,33,36-42,51,54-60 and 70-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election of species of species number 1 namely, fibrinogen, elastase inhibitor (eglin) and plasminogen, is noted. The election of aprotinin and betalactams do not apply since they apply to non-elected inventions.

Thus, claims 31, 32, 34, 35, 43-50, 52, 53, and 61-69 are withdrawn from further consideration by the examiner as being drawn to non-elected inventions.

Since applicants have not brought forth anymore arguments concerning the restriction requirement and election of species they are made FINAL.

Specification

The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) Title of the Invention.
(b) Cross-References to Related Applications.
(c) Statement Regarding Federally Sponsored Research or Development.
(d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
(e) Background of the Invention.
1. Field of the Invention.

2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(f) Brief Summary of the Invention.
(g) Brief Description of the Several Views of the Drawing(s).
(h) Detailed Description of the Invention.
(i) Claim or Claims (commencing on a separate sheet).
(j) Abstract of the Disclosure (commencing on a separate sheet).
(k) Drawings.
(l) Sequence Listing (see 37 CFR 1.821-1.825).

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:
(1) if a machine or apparatus, its organization and operation;
(2) if an article, its method of making;
(3) if a chemical compound, its identity and use;
(4) if a mixture, its ingredients;
(5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29, 30, 33, 36-42, 51, 54-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 29 is confusing since it states that the tissue adhesive is "based on" fibrinogen. What does "based on" mean ? It would be clearer if applicant simply stated " a tissue adhesive wherein said tissue adhesive contains fibrinogen and an elastase inhibitor".

The ratio in claim 36 is confusing since it is not clear what the ratio is. Is the 1:100 elastase inhibitor to fibrinogen or vise versa.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 29, 30, 33, 36-42, 51, 54-60 and 70-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hammarstrom et al. or Wadstrom in view of Robertson et al. or WO 92/22309 (WO) and further in view of Akinson et al.

Hammarstrom (see example 8 and the claims) and Wadstrom (see the abstract, col. 1, lines 1-17, col. 4, lines 45-65, and the claims) both teach tissue adhesives containing fibrinogen and plasminogen. Both tissue adhesives are used for wound healing.

Hammarstrom and Wadstrom do not teach using an elastase inhibitor in the composition as well.

Robertson (see title, abstract, col. 12, lines 3-35) and WO (see abstract, page 1, page 2) each teach that elastase inhibitors are commonly used in surgery and in wound healing.

Atkinson teaches that eglin is a well known elastase inhibitor, see cols. 1-2.

It would have been obvious to use an elastase inhibitor in the compositions of Hammarstrom and Wadstrom since both of these references are used during surgery and/or wound healing and the elastase inhibitors are also known for being used during surgery and/or wound healing according to WO and Robertson. Since one would want to enhance the effectiveness of the surgery or wound healing it would have been obvious to combine one or more ingredients each of which is known individually in the art for the same purpose to be combined together for that same purpose with the expectation of enhanced effects of the third composition formed.

It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Sussman,* 1943 C.D. 518; *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

To use eglin as the specific elastase inhibitor also would have been obvious since eglin is a well known elastase inhibitor and is commonly used by one of ordinary skill in the art. To use eglin would have clearly been within the purview of the skilled artisan in an effort to optimize the desired results of the invention. It is simply the choice of the artisan to pick eglin in the effort to optimize the results with such a well known and effective elastase inhibitor.

The adjustment of particular conventional working conditions (e.g., determining result effective amounts of the ingredients beneficially taught by the cited references, especially within the broad ranges instantly claimed), as well as using a particular type of protein on the tissue adhesive, namely, human proteins, whether the adhesive is free of kininogenic proteins, lyophilized, present in a solution, deep-frozen, virus-inactivated form, is of recombinant origin, using an application device to apply the adhesive, is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. It is clearly within the purview of the skilled artisan to make these adjustments and use these ingredients since they are merely

conditions to optimize the desired results and to attain the best effects of the claimed invention.

Accordingly, this type of modification would have been well within the purview of the skilled artisan and no more than an effort to optimize results.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Michael V. Meller
Examiner
Art Unit 1651

MVM
June 27, 2002